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THE UNITED STATES PATENT AND TRADEMARK OFFICE 2003

Applicants:

Elazar Rabbani et al.

Serial No.

09/439,594

Filed:

November 12, 1999

Title:

DETECTING THE PRESENCE OF SPECIFIC

TARGET NUCLEIC ACID SEQUENCES THORUGH STEM-LOOP FORMATION)

TECH CENTER 16 2900

Group Art Unit: 1635

Examiner: Joyce Tung

TER 1600/2900

527 Madison Avenue, 9th Floor New York, New York 10022 February 7, 2003

FILED BY EXPRESS MAIL

Honorable Commissioner of Patents and Trademarks Washington, D.C. 20231

SECOND INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. §§1.56 & 1.97-1.98

Dear Sirs:

Pursuant to the provisions of 37 C.F.R. §§1.97-1.98, and in full compliance with their duty of disclosure under 37 C.F.R. §1.56, Applicants, through their attorney, are bringing the following seven (7) documents to the attention of the U.S. Patent and Trademark Office and the Examiner handling their above-identified application:

Serial No. 09/439,594 Filed: November 12, 199

Page 2 (Second Information Disclosure Statement Under 37 C.F.R.

§§1.56 & I.97-I.98 - February 7, 2003)

RECEIVED FEB 1 1 2003 TECH CENTER 1600/2800

EXPRESS MAIL CERTIFICATE

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Deposit Date

February 7; 2003

I hereby certify that this paper and the attachments herein are being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 on the date indicated above and is addressed to the Commissioner of Patents and Trademarks, Washington DC 20231.

FEB 7 2003

Date

Ronald C. Fedus Reg. No. 32,567

Serial No. 09/439,594 Filed: November 12, 1999

Page 3 (Second Information Disclosure Statement Under 37 C.F.R. §§1.56 & I.97-I.98 – February 7, 2003)

- 1. Walker, G.T. et al., U.S. Patent No. 5,470,723 issued November 28, 1995 [Exhibit 1];
- Wilton, S.D. et al., "Snapback SSCP Analysis: Engineered Conformation Changes for the Rapid Typing of Known Mutations," <u>Human Mutation</u> 11:252-258 (1998) [Exhibit 2];
- Patel, R. et al., "Formation of chimeric DNA primer extension products by template switching onto an annealed downstream oligonucleotide," <u>Proc.</u> <u>Natl. Acad. Sci. (USA)</u> 93:2969-2974 (1996) [Exhibit 3];
- 4. Walker, G.T et al., "Strand displacement amplification an isothermal, in vitro DNA amplification technique," <u>Nucleic Acids Research 20(7)</u>:1691-1696 (1992) [Exhibit 4];
- 5. Kurfurst, R. et al., "Oligo-alpha-Deoxyribonucleotides with a Modified Nucleic Base and Covalently Linked to Reactive Agents," <u>Tetrahedron 49(32)</u>:6975-6990 (1993) [Exhibit 5];
- Nielsen, P.E. et al., "Peptide Nucleic Acids (PNA):Oligonucleotide Analogs With A Polyamide Backbone," <u>Peptide Nucleic Acids</u>, CRC Press, Inc., pages 363-373 (1993) [Exhibit 6]; and
- 7. Honeyman K. et al., "Development of a snapback method of single-stand conformation polymorphism analysis for genotyping Golden Retrievers for the X-linked muscular dystrophy allele," <u>AJVR</u> 60(6):734-737 (1999) [Exhibit 7].

The above seven documents [Exhibits 1-7] were cited in the European Search Report (annexed as Exhibit A) for the corresponding European patent application, publication number EP 0 971 039.

A completed Form PTO-1449 listing the 7 above-submitted documents is also attached hereto as Exhibit B.

By this voluntary citation of art, Applicants and their attorney are requesting that the documents be made of record in the present application.

The above citation of documents is not a representation that these documents constitute a complete or exhaustive listing, nor that the above listing ENZ-58(D1)

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necessarily includes the closest or most relevant documents, nor are these documents necessarily a complete listing of all documents known to Applicants or their attorney. It is simply a voluntary citation of documents made in good faith, which is not intended to serve in any way as a substitute for the Examiner's own search.

In view of the general and specific features described and claimed in the present application, Applicants respectfully submit that the present invention is neither disclosed nor suggested by the documents referred to above and is thus patentably distinct thereover. Furthermore, Applicants do not believe, and do not submit, by the citation of these references, that these documents, either by themselves or in combination with other documents, render the invention *prima facie* obvious under the duty of disclosure rules.

Applicants respectfully request that the Examiner make the above-submitted documents of record in the instant application. Applicants further request that the Examiner consider these documents as any of them may relate to the instant application.

The fee under 37 C.F.R. §1.17(p) for filing this Information Disclosure Statement is \$180.00. The Patent and Trademark Office is hereby authorized to charge the amount of this fee (and any other fees in connection with this IDS) to Deposit Account No. 05-1135, or to credit any overpayment thereto.

Respectfully submitted,

Ronald C. Fedus

Registration No. 32,567 Attorney for Applicants

ENZO LIFE SCIENCES, INC., f/k/a Enzo Diagnostics, Inc. c/o Enzo Biochem, Inc. 527 Madison Avenue (9th Fl.) New York, New York 10022

ENZ-58(D1)

Applicants: Elazar Rabbani et al. Serial No. 09/439,594 Group Art Unit: 1635

Filed:

November 12, 1999

Examiner: Joyce Tung

Title: NDETECTING THE PRESENCE OF SPECIFIC

TARGET NUCLEIC ACID SEQUENCES THROUGH STEM-LOOP FORMATION

TRANSMITTAL

SECOND INFORMATION DISCLOSURE STATEMENT

HON. COMMISSIONER OF PATENTS AND TRADEMARKS Washington, D.C. 20231

Sir:

Transmitted herewith is a Second Information Disclosure Statement which is being filed in accordance with 37 C.F.R. §§ 1.56 and 1.97-1.98. The items listed on Form PTO-1449, a copy of which is enclosed, may be deemed to be pertinent to the above-identified application and are made of record to assist the Patent and Trademark Office in its examination of this application. The Examiner is respectfully requested to fully consider the items and to independently ascertain their teaching.

1. [] For each of the following items listed on the enclosed copy of Form PTO-1449 that is not in the English language, an English language translation of that item or a portion thereof or a concise explanation of the relevance of that item is enclosed:

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Deposit Date

February 7, 2003

I hereby certify that this paper and the attachments herein are being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 on the date

Addressee" service under 37 CFR 1.10 on the date indicated above and is addressed to the Commissioner of Patents and Trademarks,

Washington Da 20231.

FUS 72003

Ronald C. Fedus

Date

Reg. No. 32,567

	•			
2. [] For each of the following items listed on the enclosed copy of form PTO-1449 that is not in the English language, a concise explanation of the relevance of that item is incorporated in the specification of the above-identified application.				
3.[]	Any copy of the items on the enclosed copy of Form PTO-1449 that is not enclosed with this Information Disclosure Statement was previously cited by or submitted to the Patent and Trademark Office in the prior [] Divisional or [] Continuation-In-Part application under 37 C.F.R. §1.60, U.S. Serial No, filed			
4.[]	No fee is due under 37 C.F.R. §1.17(p) for this Information Disclosure Statement since it is being filed in compliance with:			
	[]	37 C.F.R. ∍1.97(b)(1), within three months of the filing date of the above-identified application.		
	[]	37 C.F.R. $_{9}1.97(b)(2)$, within three months of the date of entry into the national stage as set forth in $_{9}1.491$ in an international application.		
	[]	37 C.F.R. \ni 1.97(b)(3), before the mailing date of a first Office action on the merits.		
5.[]	No fee is due under 37 C.F.R. \ni 1.17(p) for this Information Disclosure Statement since it is being filed in compliance with 37 C.F.R. \S 1.97(c), after the period specified in paragraph 4 above but before the mailing date of a final action or a Notice of Allowance (where there has been no prior final action), and is accompanied by one of the certifications pursuant to 37 C.F.F. \ni 1.97(e) set forth in paragraph 9 below.			
6. [x]	A fee is due under 37 C.F.R. §1.17(p) for this Information Disclosure Statement since it is being filed in compliance with 37 C.F.R. §1.97(c), after the period specified in paragraph 4 above but before the mailing date of a final action or a notice of allowance (where there has been no prior final action):			
	[]	A check in the amount of \$240.00 is enclosed in payment of the fee.		
	[x]	Charge the fee to Deposit Account No. 05-1135, Order No. ENZ-58(D1). A DUPLICATE COPY OF THIS SHEET IS ATTACHED.		

7. [] A fee is due under 37 C.F.R. §1.17(i)(1) for this Information Disclosure Statement since it is being filed in compliance with 37 C.F.R. §1.97(d), after the mailing date of a final action or a notice of allowance, whichever comes first, but before payment of the issue fee, and is accompanied by: one of the certification pursuant to 37 C.F.R. §1.97(e) set forth in a. paragraph 9 below; and the attached petition requesting consideration of this Information b. Disclosure Statement; and the fee due under 37 C.F.R. §1.17(i)(1) which is paid as set forth in C. paragraph 10 below. 8. [] A fee is due under 37 C.F.R. §1.17(i)(1) for this Information Disclosure Statement since it is being filed in compliance with: a. [] 37 C.F.R. §1.313(b)(3), after the issue fee has been paid and information cited in this Information Disclosure Statement may render at least one claim unpatentable and is accompanied by the attached Petition To Withdraw Application From Issue; b. [] 37 C.F.R. §1.313(b)(5), after the issue fee has been paid and information cited in this Information Disclosure Statement is to be considered in a Continuation application upon abandonment of the instant application and is accompanied by the attached Petition To Withdraw Application From Issue. c. [] The fee due under 37 C.F.R §1.17(i)(1) is paid as set forth in paragraph 10 below. 9. [] I hereby certify that each item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement. [] I hereby certify that no item of information in the Information Disclosure Statement filed herewith was cited in a communication from a foreign patent office in a counterpart foreign application or, to my knowledge after making reasonable inquiry, was known to any individual designated in ₃1.56(c) more than three months prior to the filing of this Information Disclosure Statement. Enz-58(D1)

10. []	A check in the amount of \$130.00 under 37 C.F.R. §1.17(i)(1).	is enclosed in payment of the fee due		
[]	Charge the fee under 37 C.F.R. Solution of the Sharper of the fee under 37 C.F.R. Sharper of the	§1.17(i)(1) to Deposit Account No. 05-1135 A DUPLICATE COPY OF THIS		
[x]		norized to charge any additional fees which on Disclosure Statement, or credit any No. 05-1135. A DUPLICATE COPY OF		
		Respectfully submitted,		
Date	d: February 7, 2003	By: RONALD C. FEDUS Registration No. 32,567		
Maili	ng Address:			
ENZO LIFE SCIENCES, INC.				

ENZO LIFE SCIENCES, INC. f/k/a Enzo Diagnostics, Inc. c/o Enzo Biochem, Inc. 292 Madison Avenue, 9th Floor New York, New York 10022 Telephone: (212) 583-0100 Telefax: (212) 583-0150